INSTRUCTIONS FOR RESEARCHERS

(Click here to navigate to the Table of Contents)

California Health and Human Services Agency

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

March 2005

Table of Contents

I. Basic Information

CPHS Web Site

All meeting agendas and announcements are posted on the CPHS web site at http://www.oshpd.ca.gov/cphs. This site also contains printable versions of CPHS Instructions for Researchers, CPHS Forms, CPHS Policies and Procedures, and links to useful resources for researchers.

CPHS Meetings

CPHS meetings are held on the first Friday of even-numbered months (February, April, June, August, October, and December) from 9:00 AM to 5:00 PM. Meetings are held in Sacramento at 1600 9th Street, Room 470, Sacramento, CA 95814. The schedule and location of upcoming meetings are available on the CPHS web site at: http://www.oshpd.ca.gov/cphs/meetings. Directions to meeting locations are provided on this page. Researchers are encouraged to appear in person, but can attend by telephone if arrangements are made in advance with the CPHS Administrator. All meetings are open to the public and conducted in compliance with the Bagley-Keene Act.

Notification of Researchers

Researchers will be notified in writing of CPHS decisions within 3 weeks of each meeting. Written responses to expedited review applications will be received within 4 weeks of receipt by the CPHS. Researchers are encouraged to contact CPHS staff with questions or comments.

Contact the Committee for the Protection of Human Subjects (CPHS)

1600 9th Street, Room 432
Sacramento, CA 95814
(916) 653-0176 (voice)
(916) 651-6222 (fax)
cphs@oshpd.ca.gov

CPHS Members

The 13 CPHS members are appointed by the Secretary of the California Health and Human Services Agency (CHHSA). Members are chosen for their expertise in differing fields of research and abilities to represent and understand the needs of diverse research subjects, particularly those who may be vulnerable due to factors such as age, socio-economic status, ethnicity, or medical conditions. CPHS is in compliance with federal regulations stipulating that: at least one member have primary concerns in scientific areas; at least one member have primary concerns in nonscientific areas; and at least one member not be affiliated with CHHSA directly or through an immediate family member. All CPHS members are required to avoid influencing or voting on committee motions regarding research proposals with which they may have conflicts of interest. Detailed information about current CPHS members is available at http://www.oshpd.ca.gov/cphs/aboutus/members.htm.

II. Mission and Purpose

The CPHS serves as the institutional review board (IRB) for the California Health and Human Services Agency. Established in 1976 in the wake of revelations about improprieties in research studies, such as the Tuskegee Syphilis Study, the role of the CPHS and other IRBs is to assure that research involving human subjects is conducted ethically. In this task the CPHS is guided by principles delineated in the *Belmont* Report, which was issued by the U.S. Department of Health, Education, and Welfare in April 1979. These principles include:

Respect for Persons

"Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy."

Beneficence

"Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being….Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms."

Justice

"…the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research."

III. Authority and Scope

Legal Authority
The CPHS operates under the terms of Federalwide Assurance (FWA) 00000681, signed in June 2001 with the U.S. Department of Health and Human Services, and conducts business, as appropriate, in compliance with the Common Rule (45 CFR Part 46 of the Code of Federal Regulations), Food and Drug Administration Regulations (21 CFR Parts 50 and 56), and the Privacy Rule of the Health Insurance Portability and Accountability Act (45 CFR Part 160).

Scope of Authority
In compliance with the Federalwide Assurance, the CPHS is obligated to review all research involving human subjects, regardless of funding source, meeting any of the following criteria:

- Research funded by CHHSA or any of its departments
- Research conducted by or under the direction of any employee or agent of the Agency or any of its departments
- Research using personally identifiable data held by CHHSA or any of its departments
- Research involving subjects for whom CHHSA or any of its departments have direct responsibility, such as patients in State hospitals.

CPHS may also review a limited number of research projects for public entities that do not meet the criteria listed above. Contact the CPHS Administrator to inquire about whether a project that does not meet these criteria may be considered for CPHS review

Reciprocity with Other Institutional Review Boards
The CPHS currently serves as the institutional review board (IRB) for selected research involving other institutions with current Federalwide Assurances (FWA) in place. CPHS has begun entering into agreements with selected IRBs to rely on those IRBs to review projects for the CPHS. If a researcher or an IRB is interested in entering into an agreement with CPHS to rely on CPHS or for CPHS to rely on another IRB, a request may be submitted in writing to the CPHS Administrator.

An IRB requesting reliance on CPHS to review a project or a class of projects may submit a cover letter requesting this arrangement along with an Authorization Agreement which has been completed and signed by the IRB's designated Institutional Official. A sample Authorization Agreement form is available on the Office of Human Research Protections web site (www.hhs.gov/ohrp/humansubjects/assurance/iprotsup.rtf). The IRB should also submit proof of having a current FWA.

If the researcher or another IRB would like to request that CPHS rely on another IRB for a project or class of projects, a written request may also be submitted to CPHS.

IV. Categories of Research

What is Research?

The Common Rule (§46.102d) defines research as: "...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether or not they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstrations and service programs may include research activities."

The key concept in this definition is "generalizable knowledge." Data collection or inquiries, which are carried out for program evaluation purposes only and are not published or otherwise widely disseminated, in general, are not considered research and thus do not require review by the CPHS. Some projects may be considered public health practice rather than research. See Public Health vs. Research Article for useful guidance on this subject. The administrator of the organization undertaking a project may decide whether a project constitutes research according to the Common Rule. However, there may be instances when it is not clear as to whether a project constitutes research. In these cases, a request can be made for the CPHS to determine whether a project constitutes research by following instructions in Section V below.

Exempt Research

The Common Rule (§46.101) exempts certain types of research from IRB review. These include:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the second bullet above if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- Research involving the collection or study of existing data, documents, records, pathological specimen, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Researchers are not permitted to independently determine that their activities satisfy these criteria for exemption. Researchers must apply to the CPHS for exemption following instructions in Section V below.

Research under HIPAA

Under the Privacy Rule of the Health Insurance Portability and Accountability Act, as of April 1, 2003, "covered entities" (health plans, health care providers, and health care information clearinghouses) cannot release protected health information for research unless the patients have signed an authorization for release or a waiver of authorization has been approved by an IRB or a Privacy Board. Some CHHSA programs are considered covered entities for HIPAA purposes and some CHHSA-funded projects use protected health information from HIPAA-covered entities. The CPHS reviews applications for waivers of authorization or alterations of authorizations under HIPAA as part of its normal review of such research projects under the Common Rule. The CPHS will not review research proposals solely for the purpose of granting waivers or alterations of authorization for HIPAA. HIPAA covered entities within CHHSA are responsible for compliance with all administrative requirements under HIPAA, including providing upon request accountings to individuals of disclosures of protected health information for research purposes.

V. Submission of Documents

General Guidelines

- All materials must be transmitted to the CPHS Administrator in printed form. Electronic submission of documents is not currently permissible, although the CPHS is interested in moving to a paperless document system in the future.

- Materials must be submitted no less than 4 weeks before the next meeting in order to be reviewed by CPHS at the meeting.

- One original and 14 copies of each document must be submitted unless you are requesting expedited review of minor changes to a previously submitted or approved project, in which case you may submit an original and 3 copies of each document.

- All documents should be submitted in a single container, with no holding or containing materials.

- Documents should be collated into complete sets that can be easily distributed to each committee member.

- All documents should be one sided unless two sided is necessary (e.g., preprinted brochures).

- Complete sets of documents should be separated with either rubber bands (the smallest that will work for that size stack) or with a staple in the TOP LEFT corner. If staples are used, please be sure the position of the staple does not interfere with reading the document. (This is especially important with two-sided documents, documents with narrow margins or thick stacks.) Please do NOT staple the original document set. Use a rubber band or, for stacks too thin for a rubber band, use a paper clip.

New Projects

Research projects that have not been previously approved by the CPHS require the submission of an original and 14 copies of the items listed below. For projects eligible for expedited review submit an original and only three copies. For information on expedited review see section VI. CPHS Processes of Review, Expedited Review.

Please Note: If a project will utilize Office of Statewide Health Planning and Development (OSHPD) data, it is highly recommended, that the draft CPHS protocol, (but not the PI's CV or other CPHS attachments) be submitted to OSHPD along with the OSHPD-required paperwork **prior** to submitting the protocol to CPHS. Please contact OSHPD Health Information Resource Center staff, Louise Hand @ 916-322-7172 or lhand@oshpd.ca.gov, to arrange this review. Subsequently, submit a copy of the preliminary approval letter obtained from OSHPD along with the project protocol to CPHS for review. Please see CPHS Bulletin #3 for a more detailed description of this process.

The following items should be submitted to CPHS in the following order:

- Cover letter addressed to the CPHS Administrator
- New Project Application and Review Checklist
- Checklists for research involving vulnerable populations (children, pregnant women and fetuses, neonates, and prisoners), if applicable. These checklists do not need to be submitted for data-only projects without human subject contact.

- Project Protocol, containing the elements listed below in the following order. (See Appendix I for a detailed description of each element)

    1. Principal Investigator
    2. Summary of the Nature and Goals of the Project
    3. Description of Human Subjects Involved in the Study
    4. Description of the Use of Human Subjects
    5. Assessment of Potential Benefits
    6. Assessment of Risks
    7. Description of Measures to Minimize Risks
    8. Health Insurance Portability and Accountability Act (HIPAA)
    9. Informed Consent
    10. Compensation
    11. Description of Medical Services Provided to Subjects
    12. Conflicts of Interest
    13. Project Budget, Source of Funding and Duration of Project
    14. Questionnaires or Interview Schedules
    15. Documentation Allowing Testing of a New Drug or Device
    16. Curriculum Vitae of Principal Investigator and Co-Principal Investigator(s)
    17. Signatures of Principal Investigator and Responsible Official

- Informed consent and/or child assent documents, containing the following elements in order. (See Appendix II for a detailed description of each element.)

    1. Purpose, Participation, and Procedures
    2. Description of Risks
    3. Confidentiality
    4. Description of Benefits
    5. Alternative Procedures
    6. Compensation
    7. Treatment for Injury
    8. Potential Conflict of Interest and Funding
    9. Questions
    10. Voluntary Participation
    11. Participant's Bill of Rights for Medical Research or Participants Bill of Rights for Non-Medical Research
    12. Consent Statement and Signature

- Additional project materials, such as informational handouts, recruitment posters, and telephone scripts (if applicable)
- Grant applications (if applicable)
- Administrative letters of support, such as a preliminary letter of approval from OSHPD (if applicable)
- Curriculum vitae of principal investigator(s)
- Resume of translator or certification of translation business (if applicable)
- Copies of relevant scientific literature (if applicable)

Continuing Projects

Previously approved projects may be reviewed for two reasons:

1. Routine periodic review (approval is for a period specified by the Committee, usually annually for low risk projects, but never for more than 364 days). Please note that projects exclusively using death data files are not subject to periodic review.

2. Review for changes to a continuing project. Please note that if a project is being submitted for changes, it may also be submitted for periodic review if it is submitted within 5 months of the expiration date of the project.

Periodic Review

One original and three copies of the documents listed below must be submitted to the CPHS in the following order if the project will be reviewed on an expedited basis (see ***Expedited Review*** in VI. CPHS Processes of Review for clarifications of which projects are eligible). If the project is designated as requiring full Committee review by CPHS, submission of one original and 14 copies of the documents listed below must be submitted in the following order. .

1. Cover letter
2. HIPAA Statement-If a waiver of patient authorization for HIPAA has been previously granted, include a statement in the cover letter as to whether there have been any changes in data security practices or other factors that might be relevant to the continuing of the waiver of authorization.
3. Continuing Project Review Form (Human Subjects Contact or Data-Only, as appropriate). If a project has ever involved human subject contact, the Continuing Project Review Form-Human Subjects Contact should be used even if human subject contact has ended.
4. Project Chronology—a dated sequence of significant events in the project's history, including all changes reviewed and approved by the CPHS
5. Protocol Summary—a short description of the basic elements of the study as currently conducted
6. Protocol-Although the CPHS approved protocol format has recently changed, continuing review projects should utilize the original format for which they were approved.
7. Informed consent and/or child assent documents
8. Summary statement of interim findings and other relevant information
9. Brief summary of recent relevant scientific literature
10. Multi-Center Study Reports, if available.

If changes to the project design or materials are proposed as part of the periodic project review, these must be described and justified in the cover letter and clean and marked-up versions of the documents must be provided as described in the next section.

Review for Changes

Proposed project changes must be reviewed and approved by the CPHS before being implemented. In the rare event that the project changes must be made without prior CPHS approval in order to protect subject safety and welfare, the

CPHS must be immediately notified. All requests for review of project changes must include:

1. Cover Letter

This should clearly describe any proposed changes to the project design and materials as previously approved by the CPHS. A clear justification should be provided for any proposed changes and an assessment should be provided of how these revisions might affect the level of risk to study participants or to the security of data.

If the Principal Investigator has changed, a conflict of interest statement should be included in the cover letter that addresses the issues in item #12 in the new project protocol (Appendix I).

2. Copies of Changed Documents

The changed documents must be provided in two forms (unless both are provided CPHS review will not be conducted):

- A clean copy with the proposed revision(s) incorporated
- A marked-up copy of the latest CPHS-approved protocol with deletions denoted by strikethrough (~~strikethrough~~) and added items denoted by underlining (underlining). The location of changes should be clearly denoted by use of indicators in the left margin or shading in the revised text.

Researchers may request expedited review of minor changes by the project's primary reviewer and the CPHS Chair or Vice-Chair. Expedited review of minor changes requires the submission of only one original and 3 copies of documents. Examples of minor changes include:

- Wording changes that do not substantially alter the meaning of project protocols, informed consent documents, or project materials
- Changes in the research period
- Changes in subject number or subject selection procedures
- Changes in database years or variables if the changes do not present additional risks of loss of confidentiality

Researchers are advised to consult with the CPHS Administrator regarding whether proposed changes qualify as minor. Project changes that are not minor must be reviewed and approved by the full CPHS in a convened session and require the submission of one original and 14 copies of documents. If the project protocol is revised, the principal investigator and the responsible institutional official must sign the original of the new clean copy.

If a project with proposed changes is subject to periodic review within 5 months of the request to the CPHS for changes, the principal investigator may request that the periodic review be performed at the same time as the review of changes. This will require that the principal investigator additionally submit all of the

documentation required for periodic review described above. If the CPHS approves the periodic review, the timing for the subsequent periodic review will be based upon the new approval date.

Completed Projects
Projects that have been successfully completed require the submission of one original and three copies of the following documents:

1. Cover Letter: This letter should summarize any results and knowledge gained from the project. Also include a description for the destruction or return of any data used in the study. If the data will be retained, explain the reason(s).

2. Continuing Project Review Form (Human Subjects Contact or Data-Only, as appropriate).

3. Copies of any reports or publications related to the research.

Please note that projects in the data and/or publication phases should not be considered completed. These projects should be considered continuing and subject to periodic review requirements.

Withdrawn Projects
Projects that have been withdrawn require the submission to the CPHS Administrator of one original and three copies of the following documents:

1. Cover letter: This should clearly summarize the reasons for withdrawal of the project.

2. Continuing Project Review Form (Human Subjects Contact or Data-Only, as Appropriate).

Determination of Research Status
To apply for determination of whether a project qualifies as research submit a letter to the CPHS Administrator addressing the following components:

- Name of the principal investigator and name of the study.
- Summary of the goals and design of the study.
- Description of the use of human subjects in the study.
- Description of the end product, such as a report or an article in a peer-reviewed journal, and/or the plan for dissemination of the project findings.

For guidance on the definition of research, see Section IV above.

Exempt Research
To apply for exemption from review, researchers are required to submit to the CPHS Administrator a letter that includes the following components:

- Name of the principal investigator and name of the study.
- Summary of the nature and goals of the study.

- Description of human subjects involved in the study.
- Description of the use of human subjects in the study.
- Rationale for exemption using the criteria specified in Section IV above.

Death Data File Projects
Projects exclusively using death data files (and without human subjects contact) require submission to the CPHS Administrator of one original and three copies of:

- Completed order form (with appropriate fee)
- Abridged research protocol (Appendix V) signed by the principal investigator and responsible institutional official
- Curriculum vitae of the principal investigator

TO:

VSAC Administrator
Department of Health Services
Office of Health Information and Research
P. O. Box 997410, MS 5103
Sacramento, CA 95899-7410
Phone (916) 552-8095

After review by the Vital Statistics Advisory Committee, these materials will be forwarded to the CPHS for review.

NOTE: For projects using other databases in addition to death data files and/or with human subjects contact submit a complete research application (see Appendix I) with an original and 3 copies for expedited review or an original and 14 copies for full committee review.

HIPAA Waiver or Alteration of Authorization
Researchers may request a waiver or alteration of patient authorization under the Health Insurance Portability and Accountability Act (HIPAA). Researchers with new project applications should complete the HIPAA section (#8) of the Research Project Protocol (Appendix I. Research Project Protocol Requirements). Researchers with continuing projects, which are not using the new protocol format, should submit a letter to the CPHS Administrator, providing:

A. A detailed description of the protected health information (including databases and variable names) to be utilized, and the HIPAA covered entity for which a waiver or alteration of authorization is required. In addition, provide justification for the data elements and the quantity of records needed for the research.

B. A description of why the research cannot practicably be conducted without the waiver or alteration.

C. A description of why the research could not practicably be conducted without access to and use of the protected health information.

D. A description of plans and measures to protect the identifiers from improper use and disclosure.

E. A statement specifying that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by HIPAA.

F. A description of plans to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

Please note that some departments, such as the Office of Statewide Health Planning and Development, are not considered covered entities under HIPAA and do not require a waiver or alteration of patient authorization. Please check with each department for guidance.

VI. CPHS Processes of Review

New Projects

CPHS review is based upon 7 criteria delineated in the Common Rule (45 CFR 46.111) listed below.

1. Risks to subjects are minimized:

    a. By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and

    b. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the CPHS will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The CPHS will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the CPHS will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disable persons, or economically or educationally disadvantaged persons.

4. Informed consent (Appendix II) will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

5. Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

6. When appropriate, the research plan will make adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

For projects involving vulnerable populations, the CPHS takes into consideration special protections delineated in the checklists, which can be found on the Forms page.

Researchers may request expedited review of projects involving data or materials previously collected for non-research purposes and that do not involve contact with human subjects.

Continuing Projects

Review of continuing projects focuses on the following issues:

1. Have adverse events been appropriately addressed by the researchers and do these events increase risk for subjects?

2. Do interim findings justify continuation of the research project?

3. Has recent literature been appropriately reviewed by the researcher and does it support continuation of the research project?

4. Are currently approved informed consent documents still accurate and complete?

5. Are a currently approved waiver or alteration of informed consent and a HIPAA waiver of authorization or alteration still justified?

Primary Reviewer System

CPHS utilizes a primary reviewer system in which one committee member is assigned to each project. This primary reviewer is responsible for initially reviewing the project, speaking with the principal investigator(s) before the committee meeting to address any questions and concerns, and presenting recommendations to the committee at convened meetings. The primary reviewer is subsequently responsible for reviewing proposed project changes and periodic continuing reviews of the project throughout its life. The primary reviewer serves as the main point of contact between the researcher and the CPHS.

Expedited Review

CPHS may utilize expedited review for projects in four circumstances:

1. Review of minor changes to a previously approved project.

2. Review of minor changes in a new project that have been delineated at a convened CPHS meeting.

3. Review of projects utilizing data or materials previously collected for non-research purposes and which do not involve contact with human subjects.

4. Periodic review of continuing projects without changes that: a) have been designated as minimal risk and no additional risks have been identified by the convened committee; b) have not yet enrolled human subjects; c) have no human subject involvement; d) have completed human subject involvement; and e) remain active only for long-term follow-up of subjects.

In circumstances 1, 2, and 3, expedited review is conducted by a subcommittee consisting of the primary reviewer and the CPHS Chair or the Vice Chair. All subcommittee members must be in agreement for approval to be granted. In circumstance 4, expedited review is conducted by the primary reviewer alone. In general, expedited review decisions will be made within 4 weeks of receipt of the documents by CPHS members. Project proposals cannot be disapproved by the expedited review process and if not approved must be referred to the full CPHS for review. The primary reviewer may contact the researcher regarding changes that will help make the proposal approvable by expedited review.

HIPAA Review

The CPHS reviews applications for waivers of authorization or alterations of authorizations under HIPAA in conjunction with the review of new and continuing research projects under the Common Rule. The CPHS will not review research proposals solely for the purpose of granting waivers or alterations of authorization for HIPAA. Documentation must be submitted as described in the Submission of Documents section above. The three criteria that must be fulfilled for a HIPAA waiver or alteration of authorization are:

1. The research involves no more than minimal risk to the privacy of individuals based on:

    - An adequate plan to protect the protected health information from improper use and disclosure.

    - An adequate plan to destroy the protected health information at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the protected health information or such retention is required by law.

    - Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted.

2. The research could not practicably be conducted without the waiver or alteration of authorization.

3. The research could not practicably be conducted without access to and use of the protected health information.

Death Data Files

Projects exclusively using death data files (without living human subjects contact) may be evaluated through an expedited review of an abridged research protocol (see Appendix V) by the CPHS Chair and one CPHS member. Once approved, projects exclusively using death data files are not subject to continuing review unless there are changes to the protocol. Researchers with projects that have previously been approved by CPHS and are subsequently requesting use of death data should revise their existing protocol to incorporate the use of the death data (see the Review for Changes section for instructions on this process).

The CPHS assesses death data file projects based upon the validity of scientific interest. The following factors are considered:

1. Does the protocol provide background information that justifies the need for the research?
2. Will the study design adequately test the principal research questions of the study?
3. Will the information requested be necessary or sufficient to answer the principal research questions?
4. Will the privacy risks to the estates of deceased persons be appropriately minimized?
5. Will the data be appropriately protected both during and after the completion of the research?
6. Will the budget be adequate to complete the research?
7. Is the principal investigator professionally qualified to carry out the research?

Convened Meetings

CPHS meetings are held on the first Friday of even-numbered months (February, April, June, August, October, and December) from 9:00AM to 5:00 PM. Meetings are held at: 1600 9th Street, Room 470, Sacramento, CA 95814. Information about upcoming meetings is available on the CPHS web site at: http://www.oshpd.ca.gov/CPHS/meetings

New Projects

For new projects, principal investigators (PI) are expected to appear in person at the scheduled meeting. Telephone attendance may be acceptable if arranged in advance with the CPHS Administrator.

Continuing Projects

For continuing projects being reviewed by expedited review, PIs are not required to appear in person unless otherwise notified by the CPHS. Telephone

attendance may be acceptable if arranged in advance with the CPHS Administrator. For projects requiring review by full committee, the PI should be prepared to appear in person or by phone, if previously arranged with the CPHS Administrator.

Bagley-Keene Act
All meetings are open to the public and conducted in compliance with the Bagley-Keene Act.

Committee Actions
The CPHS may take the following actions in convened meetings:

- Approved
- Approved pending specified minor revisions requiring only expedited review by the CPHS Chair and the project's primary reviewer
- Tabled pending resolution of significant issues that will require full committee review
- Not Approved
- Determined to be exempt research
- Determined to not be within CPHS purview

VII. Notification and Appeal

Notification of Researchers
Researchers will receive written notification of CPHS actions from the Administrator within 3 weeks after convened meetings and within 4 weeks after submission of materials for expedited review. Researchers may receive verbal communications from the CPHS at convened meetings or from individual reviewers in the course of expedited review. However, researchers should not begin implementation of a project until written approval has been received from the Administrator. Also, if the convened committee makes suggestions for changes, the researcher is expected to wait for written notification of those changes from the Administrator before submitting changes to the CPHS.

Researchers are expected to forward copies of CPHS approval notifications to departments requesting such copies. CPHS does not routinely forward copies of notifications to department staff unless they are serving as principal investigators for the project.

Appeals of CPHS Actions
CPHS decisions cannot be cancelled or altered by another institutional review board, CHHSA officials, or officials at a researcher's institution. Appeals regarding CPHS decisions should be directed to the CPHS Administrator:

Committee for the Protection of Human Subjects
1600 9th Street, Room 432
Sacramento, CA 95814
(916) 653-0176 (voice)
(916) 651-6222 (fax)

cphs@oshpd.ca.gov

VIII. Adverse Events

Reporting Requirements

Investigators are required to send written or electronic notification of an adverse event (using the Adverse Event Report Form) within 48 hours of occurrence of the event to the CPHS Administrator. This report is shared with CPHS members and is placed in the designated adverse event section of the project file.

CPHS Responsibilities

The CPHS Chair or Vice Chair and the primary reviewer of the project are responsible for determining whether immediate action needs to be taken regarding the adverse event(s). The Chair may direct the Administrator to issue a notice to the principal investigator suspending the project approval and/or take other actions deemed necessary for subject safety until the project can be reviewed by the full committee at the next meeting. After review of adverse event reports, the CPHS can order termination or revision of a project to protect the welfare and safety of subjects. The CPHS reports all serious events, as appropriate, to the Secretary of the California Health and Human Services Agency, the U.S. Office of Human Research Protection, the U.S. Food and Drug Administration, the funding agency (whether federal, state, or private), and the responsible official of the project.

Appendix I: Research Project Protocol Requirements

- The protocol must be titled with the official name of the research project.

- In the body of the protocol, information must be provided using the headings listed below. Varying the order or content of headings is not permitted. Please assure that the information provided is complete, yet concise. Sections may be denoted as "Not Applicable" as appropriate but do not skip a section or leave any section blank.

1. Principal Investigator

   Provide the principal investigator's name, title, institutional affiliation, mailing address, phone number, fax number, and e-mail address.

2. Summary of the Nature and Goals of the Project

   Include a brief statement describing the research project. Be sure to address the background for the project, including relevant literature, the major research questions to be addressed, and the expected end product (e.g., article, report or other publications).

3. Description of Human Subjects Involved in the Study

   Please provide a full description of the human subjects to be involved in the research. Issues that must be addressed include: characteristics of the human subjects (such as age, sex, ethnicity, etc.), how they will be selected or excluded, and the total number to be involved. For data-only studies, describe the data files to be used (including dates), an estimate of the total number of individual records to be used, and a list the data elements to be studied. If the research will use data files for future years, please specify the years. Provide justifications for both the quantity of the data and the data elements being requested.

   State clearly whether or not any subjects in this study will also be subjects in any other study. Please specify whether any subjects will be minors (under age 18) or members of other "vulnerable" populations, such as prisoners, pregnant women and fetuses, neonates, patients in state hospitals or developmental centers, and others who may lack the ability or competence to give voluntary informed consent. Women and members of minority groups should be appropriately included as subjects of health research projects. Reasons should be provided for not involving women, and members of minority groups (including non-English speaking groups) as subjects. Also reasons should be provided justifying involvement of minors and other vulnerable population groups in the research.

4. Description of the Use of Human Subjects

   Please describe how subjects will be involved in the research. Will they be asked to complete a questionnaire, participate in a focus group, or receive a medication or other treatment? Where and for how long will this involvement occur? If data, human tissues, or residual materials are to be used, provide the details as to their nature, origin, and disposition upon completion of the research.

5. Assessment of Potential Benefits

   Please provide a full description of the potential benefits, if any that may accrue to individual human subjects, and/or to the group or class of which subjects are members, as a result of the research. Also, describe the benefits that society and science may realize as a result of the research. Do not describe compensation as a benefit.

6. Assessment of Risks

   Provide a description of the risks, if any, to human subjects as a result of participation in the research. Risks may be physical, psychological, social, or economic and may include the loss of data security and confidentiality. If death data files are being used, include risks to the estate of the deceased person or confidentiality risks to living person by use of death data files. Please assess the likelihood, severity, and duration of risks and describe other less risky methods, if any that may be available. Why have less risky methods not been used? The level of risk (minimal, moderate, or high) must be accurately and clearly presented. Note that human subjects may be at risk for loss of confidentiality when participating in research. Even if anonymous data sets are utilized, the identity of individuals may be revealed through small cell analysis (see Appendix VI: Guidance for Using Small Numbers or Small Cells for suggested ways to handle subject confidentiality risks related to small cells or small numbers) and/or linkage to another data set. Indicate if data set(s) linkages will be established with other data sets. If the end product of the study will be in the public domain, such as a published article, how will you ensure subjects will not be identifiable?

7. Description of Measures to Minimize Risks

   Please provide a description of measures that will be taken to minimize risks to human subjects, including protecting the subjects' personal privacy and the confidentiality of information. Please describe how the researcher and any outside contractors will ensure the following:

   A. Access to data will be limited only to those with a need to know.

   B. Computer access will be protected through the use of passwords and other protections.

C. Research records will be protected through the use of locked cabinets or locked rooms, storage of identifiers separate from analysis data, and other methods.

D. Data will not be reused or provided to any persons outside of the research team.

E. Information will not be published that could possibly be used to identify an individual subject.

F. Data will be destroyed or returned as soon as it is no longer needed for the research project.

If data sets are to be linked, please provide a list of the data elements to be used. If a third party (other than the researcher or the source providing the data) will be performing the linkage of data sets, or otherwise conducting analysis, please attach a letter from the third party describing the third party's qualifications for carrying out the linkage or analysis, the procedure(s) that will be utilized, and how data security issues will be addressed in items A thru F above. If the third party has received a currently valid CPHS approval for the data linkage being used in the study then only the submission of a copy of the CPHS approval letter for that data linkage project is required.

For research involving contact with children, pregnant women and fetuses, neonates, and prisoners please complete and attach copies of the appropriate checklist(s) (children, pregnant women and fetuses, neonates, and prisoners) for vulnerable populations (see "Forms" on the CPHS web site). Do not complete these forms if the research will be limited to the analysis of pre-collected data and will not involve contact with human subjects.

8. Health Insurance Portability and Accountability Act

If applicable, attach a copy of any patient authorization forms to be used for release of protected health information under HIPAA. Please note that HIPAA authorization forms or waivers of authorization **are not required** for using data from some departments, such as the Office of Statewide Health Planning and Development that are not considered "covered entities" under HIPAA. Please check with each department regarding HIPAA requirements for use of its data**.** If a waiver or alteration of patient authorization is being requested, please provide:

A. A detailed description of the protected health information (including databases and variable names) to be utilized, and the HIPAA covered entity for which a waiver or alteration of authorization is required.

B. A description of why the research cannot practicably be conducted without the waiver or alteration.

C. A description of why the research could not practicably be conducted without access to and use of the protected health information.

***NOTE**: D, E, and F below may be answered by referring to the corresponding answers in #7 above.*

D. A description of plans and measures to protect the identifiers from improper use and disclosure.

E. A statement specifying that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by HIPAA.

F. A description of plans to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.

9. Informed Consent

Provide a description of the procedures to be used in obtaining and documenting the prior informed consent of subjects. Please refer to Appendix II for instructions on informed consent. Submit copies of written consent forms or scripts of oral instructions as attachments to this protocol. Non-English versions of forms or scripts must be submitted along with copies of the curriculum vitae of the translator(s) and/or proof of certification of the translation firm. The CPHS may reject poorly translated documents or documents from translators lacking adequate proof of training or expertise. In general, Spanish translations should use formal language.

The CPHS may approve the use of a consent procedure which does not include, or which alters, some or all of the elements of informed consent. If a waiver or alteration of informed consent is being requested, provide information as to how all of the criteria below will be satisfied:

A. The research involves no more than minimal risk to the subjects.

B. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

C. The research could not practicably be carried out without the waiver or alteration.

D. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

10. Compensation

Provide a description of any compensation to be provided to subjects for participation in the research. This should include the nature of the compensation (e.g., money, goods, or privileges), the value of the compensation, and the specific requirements of participation. Compensation should reimburse subjects for time and expenses and should not be so excessive as to be coercive.

11. Description of Medical Services Provided to Subjects

Provide a description of how medical services will be provided if the subject suffers adverse mental or physical health effects as a result of the research activity. If no such services will be provided, this should be clearly stated.

12. Conflicts of Interest

Describe any financial or other relationships of the researcher(s) or the institution that could be perceived as affecting the objective conduct of the research, including the interpretation and publication of the findings.

Financial relationships to be disclosed include but are not limited to the following:

- Present or anticipated ownership of stock, stock options, or other financial obligations of the source of funding.
- Receipt or expectation of payment of any sort in connections with papers, symposia, consulting, editing, etc. from the source of funding.
- The sale or licensing or anticipated sale or licensing of medical or other products or intellectual property, such as patents, copyrights, or trade secrets to the source of funding or other entities.
- Any past, present or anticipated receipt of money or other valuable consideration from the source of research funding by the researcher(s), the family of the researcher(s), the research institution, or by an institution in which the researcher(s) or the family of the researcher(s) has an interest as owner, creditor, or officer.

13. Project Budget, Source of Funding and Duration of Project

Provide a detailed budget, including all sources of funding and the total amount for the project. If the project is being funded as part of other operations (such as ongoing salaries and office support) or the researchers are paying costs themselves, please describe and estimate the amount of “in-kind” funding provided. If the project is a component of a larger project for which there is a separate budget, the principal investigator should provide an accurate estimate of this project's portion of that budget. Also, please specify the duration of the project in months and years. The duration should include the time required for all aspects of the project, from start-up through data analysis and final report completion.

14. Questionnaires or Interview Schedules

If questionnaires or interview schedules are to be used in the project, copies should be included as separate attachments to this protocol. If these are not available at the time of submission, a description of their content and manner of administration should be included in the protocol, along with an assurance that when completed they will be submitted to the CPHS for review and approval. Any non-English versions of questionnaires must be submitted along with copies of the curriculum vitae of the translator(s) and/or proof of certification of the translation firm. The CPHS may reject poorly translated documents or documents from translators lacking adequate proof of training or expertise. In general, Spanish translations should use formal language.

15. Documentation Allowing Testing of a New Drug or Device

If a new drug or device is to be tested or used in the research project, attach copies of state and/or federal documents that permit the investigators to proceed with the research. Describe the procedures, such as use of a data monitoring committee, to be used for adequately monitoring the safety of the subjects involved in testing a new drug or device.

16. Curriculum Vitae of Principal Investigator and Co-Principal Investigator(s)

Attach a copy of the current curriculum vitae (CV) for the principal investigator and co-principal investigator(s) after the protocol. Because of the public nature of all documents submitted to the CPHS, do not include social security numbers, home addresses**,** and other personally sensitive information.

It is not necessary to submit copies of CVs if these have been previously provided to the CPHS for a research project that has been approved within the last year and there have been no significant changes in the CV. Please provide the title and project # of the research project for which the CV has previously been submitted.

17. Signatures of Principal Investigator and Responsible Official

The protocol must be signed by the principal investigator and a responsible official of the institution or organization under the auspices of which the activity is being conducted. The responsible official must be an administrative superior to the principal investigator (e.g., department or division administrator or manager, laboratory chief, another person with administrative authority above the level of the principal investigator). The principal investigator's signature and that of the responsible official should follow a statement indicating their acceptance of responsibility and assuring that the research will be conducted in compliance with U.S. Department of Health and Human Services (DHHS) regulations for the protection of human research subjects (45 CFR 46) and decisions of the Committee for the Protection of Human Subjects. The following statement MUST be used:

"We agree to comply with and be bound by the U.S. DHHS regulations for the protection of human subjects and relevant ethical principles. We agree to comply with and be bound by all decisions of the California Health and Human Services Agency Committee for the Protection of Human Subjects."

Signature: _____
PRINCIPAL INVESTIGATOR

Name: _____

Title: _____

Date: _____

Signature: _____
RESPONSIBLE OFFICIAL

Name: _____

Title:_____

Date: _____PH #_____

E-mail: _____

Appendix II: Informed Consent and Assent

Every potential research subject (or their legally authorized representative) has the right to be fully informed of the procedures, risks, and other aspects of the research before voluntarily choosing to participate. The potential research subject (or legally authorized representative) must be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. The information provided for informed consent must be in language that is fully understandable to the subject or the legally authorized representative. Informed consent may not include exculpatory language through which the subject or the representative waives or appears to waive any legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Children 7-17 years of age must provide informed assent (as distinguished from "consent") to participate in research even if their parents or guardians have given permission for their participation through informed consent. The required elements of informed assent are very similar to the required elements of informed consent (see below).

Two Procedures for Written Informed Consent

- Regular (or "long") form**.** This is the usual type of informed consent in which the subject is presented with a detailed, printed form to read and sign that provides complete information about all required elements of consent. Regular (or "long") form consent is designed to be fully informative.

- "Short" form. In this type of informed consent the required elements of consent are explained orally to the subject by the investigator and the subject is asked to sign a form that summarizes the elements of consent. A witness must be present for the oral presentation and sign a copy of the summary. The project protocol must contain a verbatim transcript of the oral information to be presented to the subject (or legally authorized representative).

In general, the choice of "long" or "short" form consent is to be decided by the Principal Investigator based upon the risk of the research, the methodology of the research, and the characteristics and needs of the human subjects. If "short" form consent is chosen the principal investigator must provide solid justification in the project protocol.

General Principles of Written Informed Consent

- The informed consent form must begin with the official title of the research project. The title should reflect the purpose and intent of the study.

- The form should next identify the principal investigator and the institution conducting the research.

- The body of the form (elements 1-11) should be written using the pronoun "you", while the pronoun "I" should be used for the signed consent section (element 12).

Because the purpose of the consent form is to obtain consent, as well as to confirm it, the body of the informed consent form must be written in conditional language that does not read as if the potential subject has already agreed to participate.

- The form must be written in language that is fully understandable to the potential subjects. Scientific and technical terms should be avoided if simple, but equivalent words are available.

Required Elements of Informed Consent

The following elements must be included on the informed consent form using the headings as designated.

1. Purpose, Participation, and Procedures

   This section should provide: a statement that the study involves research; an explanation of the purposes of the research; an explanation of how the potential subject was selected; an approximate number of subjects to be involved; the expected duration of the subject's participation; a description of the procedures to be followed; and identification of any procedures which are experimental.

2. Description of Risks

   This section should provide a description of any reasonably foreseeable risks or discomforts to the subject. Risks may be physical, psychological, social, or economic. An assessment should be provided of the likelihood, severity, and duration of such risks. Levels of potential risk or discomfort must be accurately and clearly represented to potential subjects, and should not be unduly minimized. Any risk described in the project protocol should be addressed clearly in the informed consent form. A description should be provided of any less risky methods that were considered along with an explanation of why they will not be used. Research projects that collect or analyze personal information involve some degree of risk of loss of confidentiality for subjects. As with other risks, this should be accurately described to potential subjects.

3. Confidentiality

   This section should provide a description of any measures that will be undertaken to protect the confidentiality of human subjects involved in the research. In general, statements guaranteeing complete confidentiality should not be made to potential subjects. If records may be subject to legal challenges, or certain information must be reported to law enforcement officials, this should be stated. If a federal certificate of confidentiality will be obtained, this should be described in this section.

4. Description of Benefits

   This section should provide a description of any benefits to the subject or others that may be reasonably expected to result from the research. Neither compensation for participation in the activity nor the absence of costs or charges to subjects may be

portrayed as benefits. If no benefits for the subjects are expected, that should be clearly stated.

5. Alternative Procedures

This section should describe any similar or equivalent procedures or treatments that may be available to potential research subjects who do not choose to participate in the research. For example, potential subjects may be able to request a similar test or treatment from their personal physician. If no alternative procedures or treatments are available, that should be stated.

6. Compensation

This section should clearly describe the value and circumstances for receipt of any money or other compensation for participation in the study. If no compensation is to be received, this should be stated. The absence of costs or charges to the subject cannot be considered compensation.

7. Treatment for Injury

If the research is greater than minimal risk, describe any treatment that will be available if any injury occurs to the subject as a result of the research and provide information about where treatment information may be obtained. If treatment will not be available, this should be stated.

8. Potential Conflict of Interest and Funding

This section should describe any financial or other relationship interests the researcher may have that may potentially affect the performance of the research or how results of the research are interpreted. In addition, the funding source or sponsor of the research must be identified.

9. Questions

This section should provide information about: 1) who to contact with questions about the research (usually the principal investigator), and 2) who to contact with questions about research subjects' rights (usually an institutional review board, an ethics board, or other oversight panel). If another board or panel is not reviewing the project, the subjects may be instructed to contact: Administrator, Committee for the Protection of Human Subjects, California Health and Human Services Agency (916-653-0176, cphs@oshpd.ca.gov) for information about research subjects' rights.

10. Voluntary Participation

This section should provide a clear statement that participation in the research is voluntary and that refusal to participate or withdrawal from the research at any point will not result in any penalty or loss of benefits to which the subject is otherwise entitled.

11. Research Participant's Bill of Rights

This section should include a statement that the subject is being given a copy of the Research Participant's Bill of Rights in addition to the informed consent form. For medical experiments California law (Health and Safety Code, Section 24172) requires that the "California Research Participant's Bill of Rights" (Appendix III) be used. The Spanish version of this document is also included in Appendix III. Medical experiments are defined in Section 24174 as:

"(a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, as defined in Section 109920 or 109925, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.

(b) The investigational use of a drug or device as provided in Sections 111590 and 111595.

(c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject."

For non-medical research the "Research Participant's Bill of Rights for Non-Medical Research" (Appendix IV) should be used. The Spanish version of this document is also included in Appendix IV. The researcher may submit alternative versions of the bill of rights for non-medical research for CPHS approval.

A copy of the approved medical or non-medical bill of rights must be attached to the consent form given to the subject.

12. Consent Statement and Signature

This is a signed and dated statement that the subject gives consent to participate in the research study and has received a copy of the Research Participant's Bill of Rights. For this statement the pronoun "I" should be used. If applicable, space should be provided for the signature of a witness. In certain circumstances the signatures of both parents may be required for children who are involved in research (see CFR §46.408).

Additional Elements of Informed Consent

When appropriate, information on one or more of the following elements should be included in the consent form:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.

2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without the subject's consent.

3. Any additional costs to the subject that may result from participation in the research.

4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

5. A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.

6. For research involving subjects with severe psychiatric disorders: a statement regarding (a) whether the treating psychiatrists are also members of the research team, and (b) whether study medications are determined by clinical need or dictated by the research protocol.

7. For research involving test articles regulated by the Food and Drug Administration (FDA): a statement that the purpose of the study includes evaluation of both the safety and the effectiveness of the test article.

8. Specifics on the methods, amounts, and timing of any proposed taking of blood or any other human materials, and their subsequent disposal.

9. Details regarding authorization for access to the subject’s personal records (school, university, hospital and employment, or others).

10. Details regarding the use of tape recorders or other audio or visual recordings, and an explanation of the proposed uses and disposition of such materials.

11. Assurance that should the investigator discover any untoward medical condition or inheritable disorder in the subject, this will be brought, if possible, to the attention of the subject’s own physician, or the subject will be informed of the condition and advised to seek proper assistance.

<u>Informed Assent</u>

While the intent of informed assent is the same as that of informed consent, the informed assent form must be written at a level that is understandable to potential subjects who are children between 7-17 years of age. Different informed assent forms may be needed if the study involves children of significantly different ages.

The same headings must be used as for informed consent. Because some children cannot read through as long a form as an adult, assent forms may be shortened to facilitate reading and understanding by children. However, all of the required elements of the informed consent still must be adequately addressed.

Waiver or Alteration of Informed Consent

The CPHS may approve the use of a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent if Criteria A or Criteria B (below) apply.

Criteria A.

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs; and

2. The research could not practicably be carried out without the waiver or alteration.

Criteria B

1. The research involves no more than minimal risk to the subjects;

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3. The research could not practicably be carried out without the waiver or alteration; and

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

<u>Waiver of Written Informed Consent</u>

The CPHS may grant a waiver of the requirement for written informed consent under carefully justified circumstances as follows:

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject must be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Examples of projects for which the CPHS may consider requests for waivers of written consent include: projects in which the research subjects are illiterate; projects in which the risks (usually psychological risks) inherent in asking subjects for their signatures outweigh the risks of not obtaining the signatures; projects in which requests for

signatures demonstrably violate or distort the subjects' perceptions of the nature and purpose of the investigation; and interview studies in which the subjects will read and keep the information contained in a consent document.

The waiver of written informed consent does not eliminate the investigator's ethical and legal obligation to obtain the prior consent of subjects for participation in the research activity.

Appendix III: Participant's Bill of Rights for Medical Research

Any person who is asked to participate as a human subject in a research study, or who is asked to consent on behalf of another, has the following rights:

(a) Be informed of the nature and purpose of the study.

(b) Be given an explanation of the procedures to be followed in the study, and any drug or device to be utilized.

(c) Be given a description of any attendant discomforts and risks reasonably to be expected from the study.

(d) Be given an explanation of any benefits to the subject reasonably to be expected from the study, if applicable.

(e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

(f) Be informed of the avenues of medical treatment, if any, available to the subject after the study if complications should arise.

(g) Be given an opportunity to ask any questions concerning the study or the procedures involved.

(h) Be instructed that consent to participate in the study may be withdrawn at any time and the subject may discontinue participation in the study without prejudice.

(i) Be given a copy of the signed and dated written consent form.

(j) Be given the opportunity to decide to consent or not to consent to a study without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

(Adapted for a research project from Health & Safety Code Chapter 1.3, Section 24172)

Declaración de Derechos de Participantes en estudios Investigación Medicas
(Spanish translation of Participant's Bill of Rights for Medical Research)

Bajo la Ley de California, toda persona a quien se le pida participar en un estudio de investigación, como participante o sujeto experimental, tiene los siguientes derechos:

a) Debe ser informado de la naturaleza y propósito de la investigación.

b) Debe ser informado de lo que pasará durante el estudio, e informársele acerca de drogas o instrumentos que serán usados.

c) Debe ser informado de los riesgos o malestares que los procedirnientos del estudio le puedan causar al participante.

d) Debe ser informado de cualquier beneficio que el participante pueda esperar del estudio.

e) Debe ser informado de otras alternativas en los procedimientos, drogas, o instrumentos que puedan ser útiles al participante y sus posibles riesgos o beneficios.

f) Debe ser informado de tratamiento médico, si es que hay alguno, disponible al participante durante y al final del estudio, en caso de que surjan complicaciones.

g) Se le debe permitir hacer preguntas concernientes al estudio, y acerca del procedimiento.

h) Debe ser informado de que puede retirarse del estudio, en cualquier momento que el participante decida, y de que tal decisión no lo afectará.

i) Si accede a participar, debe recibir una copia de la forma de consentimiento fechada y firmada.

j) Debe estar libre de presiones,o elementos de fuerza, engaños, fraude u otras influencias, al decidir de si participa o no en el estudio o experimento.

(Adapted for a research project from Health & Safety Code Chapter 1.3, Section 241 72)

(Traducido por F.Cordero)

Appendix IV: Participant's Bill of Rights for Non-Medical Research

You have been asked to participate in a research study. Any participant in a research study has the right to:

(a) Be told the nature and purpose of the study.

(b) Be given an explanation of what will happen during the study and of how the research participant is expected to participate.

(c) Be given an explanation of any risks or discomforts that may be experienced as a result of participating in the study.

(d) Be given an explanation of any benefits that may be expected from participation in the study.

(e) Be told of other appropriate choices that may be better or worse than being in the study, and be told of the risks and benefits of those other choices.

(f) Have the opportunity to ask questions about the study or about your participation in it, both before agreeing to participate in the study and during the course of the study.

(g) Be told that you may withdraw your consent and participation in the study at any time, and that your withdrawal will not affect your services.

(h) Be told that you may refuse to answer any question.

(i) Be given a copy of the signed and dated consent form.

(j) Be free of pressure when considering whether to consent to, and participate in, the study.

(k) Be informed, upon request, about the results of the study.

Declaración de Derechos de Participantes en estudios Nomedicos
(Spanish translation of Participant's Bill of Rights for Non-Medical Research)

Se le ha pedido que participe en un estudio de investigación. Cualquier participante en un estudio de investigación tiene el derecho a:

(a) Que se le diga la naturaleza y el propósito del estudio.

(b) Que se le dé una explicación de lo que ocurrirá durante el estudio y de que manera se espera que participe el participante en una investigación.

(c) Que se le dé una explicación de todos los riesgos o molestias que pueden ocurrir como resultado de la participación en el estudio.

(d) Que se le dé una explicación de todos los beneficios que se pueden recibir de la participación en el estudio.

(e) Que se le diga de otras alternativas apropiadas que pudieran ser mejores o peores que la participación en el estudio, y que se le diga de los riesgos y beneficios de esas otras alternativas.

(f) Que tenga la oportunidad de hacer preguntas acerca del estudio o acerca de su participación en el estudio, antes de participar en el estudio y durante la duración del estudio.

(g) Que se le diga que puede retirar su consentimiento y participación en el estudio en cualquier momento, y que su retiro no le afectará sus servicios.

(h) Que se le diga que puede rehusarse a contestar cualquier pregunta.

(i) Que se le dé una copia firmada y fechada de la forma de consentimiento.

(j) Estar libre de presiones al momento de decidir si da su consentimiento para participar en el estudio.

(k) Obtener información, en cuanto usted lo pida, acerca de los resultados del estudio.

(Traducido por J. Ruiz)

Appendix V: Research Protocol Requirements for Projects Involving Death Data Files Without Human Subject Contact

Identifying Information

- The *project title* should be prominently displayed at the top of the protocol.
- The principal investigator's name, title, address, telephone and fax numbers, and e-mail address should be provided at the beginning of the protocol.

Main Body of Protocol--the protocol must contain the following information and use the following headings:

1. Summary of Nature and Goals of the Study

   Please describe the basic research design of the project, including background information, justifying the need for the research and the principle hypothesis(s) to be tested. Describe potential benefits to society of the study.

2. Description of Data to be Utilized in the Study

   Please list the relevant variables in the death data file and describe how they will be used in the research. If these variables will be linked with variables in other data files please describe the methodology and rationale for this linking. Describe the number of records and the period(s) of time for which the data is being requested. If the project will require use of future databases, specify the dates of these databases in this section.

3. Description of Privacy Risks and Measures to be Taken to Minimize Risk

   Please describe any privacy risks to the estates of deceased persons or to the confidentiality of living persons presented by use of death file data for research. Describe how data will be protected, including the use of password protected computers, locked filing cabinets, and other access control. Describe how data will be destroyed or securely stored after completion of the research. Describe the qualifications of all persons who will have access to the data.

4. Project Budget, Source of Funding and Duration of Project

   Please provide a line item budget of all expenses of the project and the primary sources of funding. If the project duration will exceed one year, please specify a separate budget for subsequent years. If a project is not being funded separately from other operations, and is instead funded through an ongoing budget, or the researchers intend to pay the costs themselves, please describe. If exact amounts are not available, please estimate.

5. Signature of Principal Investigator and Responsible Official

The protocol must be signed by the principal investigator and a responsible official of the institution or organization under the auspices of which the activity is being conducted. The responsible official must be an administrative superior to the principal investigator. The principal investigator's signature and that of the responsible official shall follow the statement below:

"We certify that all information in this protocol is true and agree to comply with and be bound by all decisions of the California Health and Human Services Agency Committee for the Protection of Human Subjects."

Signature: _____
PRINCIPAL INVESTIGATOR

Name: _____

Title: _____

Date: _____

Signature: _____
RESPONSIBLE OFFICIAL

Name: _____

Title: _____

Date: _____

Phone:_____

E-Mail:_____

Curriculum Vitae of Principal Investigator: All protocols must be accompanied by a current curriculum vitae of the principal investigator and all co-principal investigators.

Appendix VI: Guidance for Using Small Numbers or Small Cells

GUIDANCE FOR USING SMALL NUMBERS OR SMALL CELLS

Definition of a small cell or a small number

- A *cell* is the intersection of a row and a column in a table, a spreadsheet, or in any matrix of numbers. For example, a table with four rows and three columns has twelve cells;
- The CPHS considers a cell *small* when it contains 1 to 15 research subjects*;*
- Some projects do not report data as tables but still might describe the characteristics of *small numbers* of subjects. Whenever a project describes 1 to 15 subjects it is important to be especially careful that the identities of all subjects are protected from possible disclosure.

Why small numbers or small cells are potential problems

A *small number* of subjects in a descriptive report or *small cells* in a table could potentially lead to the unintended identification of a research subject's identity. With a small study population, or with a small subset of a larger population, researchers should be careful about possibly identifying subjects. For example, research subjects in a rural community might be easily identified because their community has only one or two instances of a particular disease. Similarly, multiple tables describing an urban community might allow for the deduction of a subject's identity through a process of subtraction involving cells if the numbers in them are sufficiently small.

Suggested methods for dealing with small cells or small numbers

- Eliminate tables with *small cells* or data descriptions with *small numbers*: Within a table, combine (collapse) the row (or column) containing a *small cell* with another row (or column) to increase cell size;
- Combine the different time periods, such as fiscal years, represented by two or more tables (or descriptions) into a single table (or description) to increase cell size (or number size);
- Suppress a *small cell* with a non-numeric symbol that hides the number of subjects, (for example {sc}). To prevent the identification of a small cell through subtraction, the suppression symbol should appear at least twice in the row and column of each of its intersections, as in the following example.

	> 65 yrs	18-64 yrs	< 18 yrs	TOTAL
agree	{sc}	30	{sc}	60
neutral	{sc}	60	{sc}	150
disagree	70	90	80	240
undecided	0	0	0	0
TOTAL	120	180	150	450

- Use of these suggested methods is recommended but not required by the CPHS. Researchers may request approval from CPHS for using alternative methods to protect subject identity when using small cells or small numbers.